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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,824	09/08/2000	Tongtong Wang	210121.478C11	2868

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/02/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,824

Applicant(s)

WANG ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

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RESTRICTION

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the method claims in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods require the detection of distinct target molecules or the use of distinct reagents. A reference against one target molecule would not be a reference against the other target molecule.

Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 3, 4, 8, 11, and 15, drawn to nucleic acids, classified in Class 536, subclass 23.5.

II. Claims 2, 7, and 11, drawn to proteins, classified in Class 530, subclass 350.

III. Claims 5, 11 and 16, drawn to antibodies, classified in Class 530, subclass 387.

IV. Claim 6, drawn to methods to detect cancer by detecting a protein, classified in Class 435, subclass 71.,

V. Claims 9, 12, and 13 drawn to a method to stimulate T cells by contacting the cells with a protein, classified in Class 514, subclass 12.

VI. Claim 9, 12, and 13, drawn to a method of stimulating T cells by contacting the cells with a nucleic acid, classified in Class 514, subclass 44.

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VII. Claims 9, 12 and 13, drawn to a method of stimulating T cells by contacting the cells with an antigen presenting cell, classified in Class 424, subclass 93.21.

VIII. Claim 10, drawn to a population of T cells, classified in Class 424, subclass 93.21.

IX. Claim 11, drawn to a population of antigen presenting cells, classified in Class 424, subclass 93.21.

X. Claims 12 and 13, drawn to methods of stimulating an immune response and treating cancer using an antibody, classified in Class 424, subclass 138.1.

XI. Claims 12 and 13, drawn to methods of stimulating an immune response and treating cancer with T cells, classified in Class 424, subclass 93.21.

XII. Claim 14, drawn to a method of detecting cancer by detecting a nucleic acid, classified in Class 435, subclass 6.

XIII. Claim 17, drawn to a method of inhibiting cancer by treating CD4+ or CD8+ cells with a protein, classified in Class 514, subclass 12.

XIV. Claim 17, drawn to a method of inhibiting cancer by treating CD4+ or CD8+ cells with a nucleic acid, classified in Class 514, subclass 44.

XV. Claim 17, drawn to a method of inhibiting cancer by treating CD4+ or CD8+ cells with an antigen presenting cell, classified in Class 424, subclass 93.21.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct in structure and physicochemical properties.

Invention I is drawn to nucleic acids whereas invention III is drawn to proteins. Because nucleic

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acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention II do not require the particular products of the nucleic acids of invention I since the proteins of invention II can be isolated from natural sources or chemically synthesized.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to make the antibodies of invention III. Furthermore, the different inventions are not disclosed as capable of use together and have different functions and have different physical and structural properties.

Inventions I and VI and I and XII and I and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins, or for therapeutic methods.

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Inventions I and IV, I and V, VI, I and VII, I and X, I and XI, I and XIII, and I and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to practice the methods of inventions IV, VI, VII or X, XI, XIII or XV.

Inventions I and VIII and I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of invention I are not required to make the cells of invention VIII and IX. Furthermore, the different inventions have different functions and have different physical and structural properties.

Inventions II and III are patentably distinct in structure in that the proteins of invention III have a different amino acid sequence as compared to the antibodies of invention IV. Furthermore, the products of invention II and III are utilized in different methodologies, such that the proteins may be utilized in ligand binding assays and the antibodies may be used in therapeutic methods. Synthesis of the antibodies of invention III does not require the particular products of the proteins of invention II since the antibodies of invention III can be isolated from natural sources.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for generating antibodies or for therapeutic purposes.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for generating antibodies or for diagnostic purposes.

Inventions II and VI, II and VII, II and X, II and XI, II and XII, II and XIV and II and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention II are not required to practice the methods of inventions VI, VII, X, XI, XII, XIV and XV.

Inventions II and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

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§ 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for generating or detecting antibodies or for diagnostic purposes.

Inventions II and VIII and I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the proteins of invention II are not required to make the cells of invention VIII and IX. Furthermore, the different inventions have different functions and have different physical and structural properties and can be utilized in different methods.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for therapeutic uses.

Inventions III and V, III and VI, III and VII, III and XI, III and XII, III and XIV and III and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to practice the methods of invention V, VI, VII, XI, XII, XIV or XV.

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Inventions III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as for diagnostic uses.

Inventions III and VIII and III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of invention III are not required to make the cells of invention VIII and IX. Furthermore, the different inventions have different functions and have different physical and structural properties.

Inventions IV, V, VI, VII, X, IX, XII, XIII, XIV, and XV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to distinct methods, each requiring different reagents, involving different method steps and having different objectives.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the T cell population and the antigen presenting cells of inventions VIII and IX different functions and have different physical and structural properties and may be utilized in distinct methods.

Inventions VIII and X, VIII and XII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions In the instant case, the different inventions are not disclosed as capable of use together because the T cells of invention VIII are not required to practice the methods of inventions X or XII.

Inventions VIII and XI, VIII and XIII, VIII and XIV and VIII and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the T cells of invention VIII can be used in a materially different process, such as for methods of screening for therapeutics.

Inventions IX and X, IX and XI, IX and XII, IX and XIII, IX and XIV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

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(MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions In the instant case, the different inventions are not disclosed as capable of use together because the antigen presenting cells of invention IX are not required to practice the methods of inventions X, XI, XII, XIII, or XIV.

Inventions IX and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)). In the instant case, the antigen presenting cells of invention XV can be used in a materially different process, such as for methods of screening for therapeutics.

2.

Sequence Election Requirement Applicable to All Groups

In addition, each inventions detailed above each read on patentably distinct inventions drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each invention. For an elected invention drawn to a nucleic acid or amino acid sequences, Applicants must further elect a single nucleic acid or amino acid sequence. For example, if Applicant elects invention I, Applicant must further elect a single nucleic acid sequence selected from the group of SEQ ID NO's: 1680-1788.

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It is noted that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

3. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XV require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.
4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

July 1, 2002


CARLA J. MYERS
PRIMARY EXAMINER